

REMARKS

Initially, Applicants have amended independent claims 1 and 11 to add the provision that the binder, the lubricant, the solvent and the effective veterinary agent are homogenously distributed throughout said film. Support for this amendment can be found in Applicant's original specification on page 7, lines 9-11 and p. 8 lines 21 to p. 9 line 1.

With respect to the nonstatutory obviousness-type double patenting rejection of claims 1-14 as being unpatentable over claims 1-8 of U.S. Patent No. 7,005,142 to Leon et al. in view of U.S. Patent No. 6,596,298 to Leung, Applicants will submit a Terminal Disclaimer with the terminal disclaimer fee pursuant to 37 C.F.R. 1.20(d) in the near future.

Applicants respectfully request reconsideration of the rejection of claims 1-13 under 35 U.S.C. § 103(a) over the '298 patent to Leung et al. in view of the '237 patent to Gould et al., with continued citation to and reliance on the '549 patent to Lewandowski.

The Office Action's application of these two references is contrary to the Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc. (hereinafter the "KSR Guidelines"), as well as MPEP § 2141.02, both of which require that prior art references be considered in their entireties, i.e. as a whole.

The KSR Guidelines state:

“Ascertaining the differences between the claimed invention and the prior art requires interpreting the claim language, and considering both the invention and the prior art as a whole.” Federal Register Vol. 72, No. 195, p. 57528; see also MPEP §2141 (II)(B).

In addition, §2141.02 of the MPEP states:

“A prior art reference must be considered in its entirety, i.e. as a whole, including portions that would lead away from the claimed invention.” MPEP §2141.02(VI) (emphasis in original).

The Office Action states:

“The secondary reference was relied upon simply to show that, in the field of oral mucosal delivery, the skilled artisan knows that treatments useful with humans are likewise useful for animals, and vice versa. Applicant’s focusing on specific technical differences represents a “piecemeal” analysis of the individual references which ignores this fact.”

While asserting that Applicants have engaged in “piecemeal” analysis of the references, it is the Office Action which carves one select piece out of the Gould teaching, i.e, use of a film on a non-human, and attempts to use this dissected piece to patch the gaping hole in the teaching of the Leung reference. In doing so, the Office Action has used Applicants’ present application as a template for its own reconstruction. It is this type of piecemeal analysis which has long been prohibited by the Courts and the MPEP. The Court of Appeals for the Federal Circuit has cautioned against improper use of Applicants’ own patent application as a template upon which an obviousness type rejection is built. For example, in *Sensonics, Inc. v. Aerosonic Corp.*, 38 USPQ2d 1551, 1554 (Fed. Cir. 1986), which is still good law, the Court of Appeals for the Federal Circuit stated:

“To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction - an illogical and inappropriate process by which to determine patentability. *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 220 USPQ 303, 312-13 (Fed. Cir. 1983). The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made.”

Gould has not been considered in its entirety as one of ordinary skill would have done if he did not have the benefit of seeing Applicants’ invention before hand. Unlike the Office Action, Applicants are viewing each of the references in their entireties and against the backdrop illuminated by the known prior art.

The proposition that “treatments useful with humans are likewise useful for animals, and vice versa” is untenable in light of the teachings of Lewandowski which shows that using a product which provides one effect on humans can have an opposite effect on non-human mammals. Lewandowski states:

“the present invention arose from domestic canine feeding research conducted by the inventor and has lead *to the counterintuitive result* that ingestion of raw garlic powder by dogs largely eliminates the bad breath ...”

(See col. 2, lines 34-37). Presumably, the use of garlic powder was counterintuitive because of garlic’s known effects on the breath of humans.

Moreover, when Gould is properly considered in its entirety as required by the MPEP and KSR Guidelines, it is clear that these two references are not properly combinable in view their contrary teachings. The ‘237 patent to Gould is directed to delivery systems which provide controlled “zero order” release of pharmaceutically active compounds, i.e. a slow, steady release of the active compounds as opposed to a

rapid initial release followed by a quickly declining release of the active compounds. ('237 patent, col. 1, lines 49-51). To accomplish this Gould et al. provides a diffusion barrier film (layer 14) to or around an inner drug bearing layer (12). ('237 patent, col. 2, lines 22-31). Gould teaches that films that do not have a diffusion barrier would lack his desired release rate of pharmaceutically active compounds. Gould states:

“The incorporation of pharmaceutically active compounds in high molecular weight water-sensitive polymers to prolong release therefrom is known in the art. However, most frequently, the release profile follows first order kinetics and a high initial rate decays rapidly as the concentration of drug in the polymer decreases.” ‘237 patent, col. 1, lines 39-44.

All of Gould’s embodiments have a diffusion barrier. This is the whole point of Gould’s patent. To the contrary, Leung is directed to a rapid release film. Leung neither teaches nor suggests the use of its strips on non-human mammals and Gould does not teach or suggest the use of the strips disclosed in Leung on non-human mammals. The purpose and nature of these patents, as clearly indicated in their titles and in their disclosures, is exactly opposite. Where the ‘298 Leung et al. patent is directed to a film which dissolves fast, the ‘237 Gould et al. patent is directed to long term release.

The proposed combination of references in this Office Action is not a case where only one of the cited references has a single embodiment with a contrary teaching.

MPEP §2141.02 (VI) states:

“the prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...”

In this case, every one of Gould's many embodiments comprises a diffusion barrier to slow down the release of the active compound. Gould teaches that its products must have a diffusion barrier in order to have the desired efficacy. Using a film that does not have a diffusion barrier, such as the homogenous film of Leung, would be inappropriate because it would not provide the controlled zero order release intended by the film taught by Gould.

Moreover, the §103 rejection is also improper because the Office Action improperly assumed the existence of market pressure. A need or market pressure for ameliorating bad breath in non-human animals cannot possibly emanate from a document which purports to provide a quick and inexpensive solution to that need. The Office Action cites the Lewandowski patent as evidence of an existing "need" to treat "doggy breath." This argument ignores the very teaching of the evidence upon which it relies. Lewandowski provided a solution to meet that "need" so one of ordinary skill would assume that this "need" had already been satisfied. Market pressure does not exist simply because a prior art reference teaches a solution.

Therefore, these references are not properly combinable and would surely not have lead one of ordinary skill in the art to Applicants' claimed method of treating an illness in a *non-human* mammal with a film comprising homogenously distributed ingredients. The Lewandowski patent would not have provided one of ordinary skill in the art with an incentive to try Applicants' claimed invention.

CONCLUSION

Applicant respectfully submits that all pending claims as amended are now in condition for allowance. If the Examiner has any questions or comments which might expedite the prosecution of the present application, he is respectfully invited to contact the Applicants' attorney on the phone number set forth below.

Respectfully submitted,

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